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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,742	02/19/2004	Yoshihiro Inaba	118754	1791

25944 7590 10/07/2005

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ALEXANDRIA, VA 22320

EXAMINER
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BOYKIN, TERRESSA M

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/780,742

Applicant(s)

INABA ET AL.

Examiner

Terressa M. Boykin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**Priority**

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United

**Claims 1-16 are rejected under 35 U.S.C. 102(b, or e) as being anticipated by Lanciotti et al. see abstract and page 100 or Kyo et al. abstract and page 156 .**

Lanciotti discloses a bifunction polyethylene glycol. Note the reference states:

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Bifunctional PEG (polyethylene glycol) molecules provide a novel approach to retargeting viral vectors without the need to genetically modify the vector. In a previous report we showed that modification of the viral capsid by the addition of a peptide with binding preference for differentiated ciliated airway epithelia allowed gene delivery to those cells by a novel entry pathway. Here we demonstrate further the versatility of this method by coupling a protein, FGF2, to the surface of an adenovirus (Ad). This modification results in the elimination of the endogenous tropism of the virus and confers upon the virus a novel route of entry. Adenoviral vectors modified by the addition of FGF2 show enhanced efficiency of transduction of the ovarian cancer cell line SKOV3.ip1. This enhancement in transduction is dependent on the binding of the coupled FGF2 to its high-affinity receptor and is independent of coxsackie and adenovirus viral receptors. In an intraperitoneal model of ovarian cancer, Ad/PEG/FGF2 generates increased transgene expression in tumor tissue compared to unmodified Ad. Furthermore, polymer modification of adenovirus vectors results in reduced localization of adenovirus to nontarget tissues and a marked decrease in Th1 and Th2 T cell responses. In conclusion, the approach described here may lead to the development of a gene therapy vector capable of targeting a therapeutic gene to diseased cells, while minimizing toxicity and expression in other tissues.

Note page 100 discloses the particular structure as claimed.

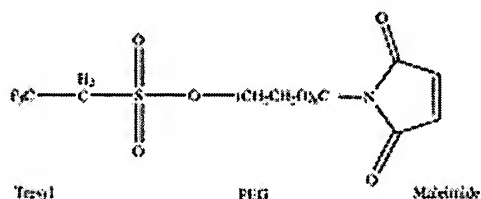


FIG. 1. Schematic diagram of tressyl-PEG-maleimide (TMPEG-mal). The bifunctional PEG molecule TMPEG-mal is shown. This molecule has two reactive groups; the tressyl group is reactive toward  $\epsilon$  amino groups on the capsid of adenovirus while the maleimide group is reactive toward available cysteines on the surface of the FGF2 molecule.

Kyo discloses evaluation of MafG interaction with Maf recognition element arrays surface plasmon resonance imaging technique. Note the reference states:

Specific interactions between transcription factors and *cis*-acting DNA sequence motifs are primary events for the transcriptional regulation. Many regulatory elements appear to diverge from the most optimal recognition sequences. To evaluate affinities of a transcription factor to various suboptimal sequences, we have developed a new detection method based on the surface plasmon resonance (SPR) imaging technique. Transcription factor MafG and its recognition sequence MARE (*Maf* recognition elements) were adopted to evaluate the new method. We modified DNA immobilization procedure on to the gold chip, so that a double-stranded DNA array was successfully fabricated. We further found that a hydrophilic flexible spacer composed of the poly (ethylene glycol) moiety between DNA and alkanethiol self-assembled monolayers on the surface is effective for preventing nonspecific adsorption and facilitating specific binding of MafG. Multiple interaction profiles between MafG and six of MARE-related sequences were observed by the SPR imaging technique. The kinetic values obtained by SPR imaging showed very good correlation with those obtained from electrophoretic gel mobility shift assays, although absolute values were deviated from each other. These results demonstrate that the double-stranded DNA array fabricated with the modified multistep procedure can be applied for the comprehensive analysis of the transcription factor-DNA interaction.

on page 156 the reference discloses the structures:

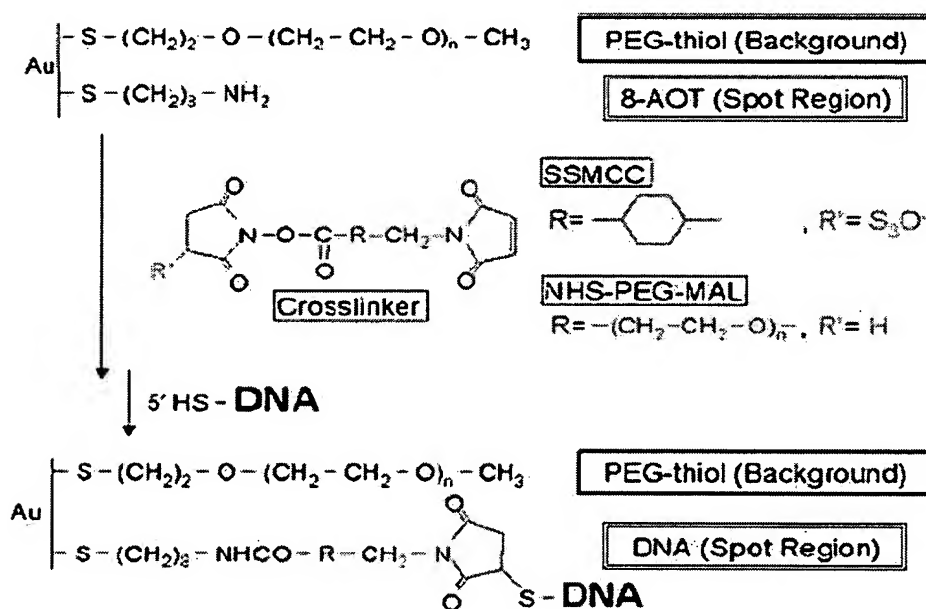


Figure 2 Two different hetero crosslinkers for specific binding to DNA array. Two hetero crosslinkers sulfosuccinimide maleimide methylcyclohexane-1 (SSMCC) and N-hydroxysuccinimide maleimide MW 3400 (NHS-PEG-MAL), were tested for the immobilization of 5'-thiol modified oligo. SSMCC provides a hydrophilic linker, while NHS-PEG-MAL provides a hydrophilic and flexible spacer.

Each of the references discloses a maleimide group-containing crosslinked polymer as claimed by applicants. Since the disclosed particle amounts are expressed differently and thus may be distinct from those claimed, it is incumbent upon applicant(s) to establish that they are in fact different and whether such

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difference is unobvious. In view of the above, there appears to be no significant difference between the reference(s) and that which is claimed by applicant(s).

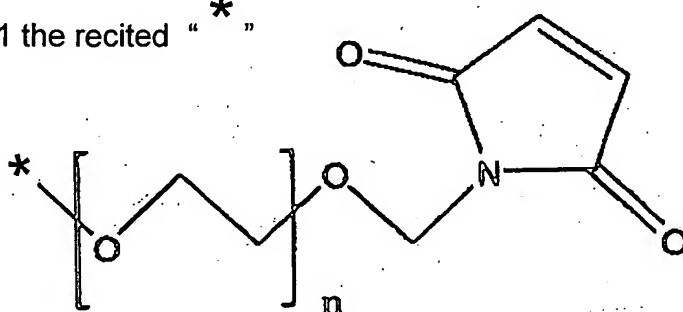
Any differences not specifically mentioned appear to be conventional.

Consequently, the claimed invention cannot be deemed as novel and accordingly is unpatentable.

### **35 USC 112, Second Paragraph**

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the recited “ \*



is undefined and accordingly unclear with regard to its intended meaning.

### **Correspondence**

Please note that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources. Applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Terressa Boykin whose telephone number is 571 272-1069. The examiner can normally be reached on Monday through Friday from 6:30am to 3:00pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. The general information number for listings of personnel is ( 571-272-1700).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

tmb

  
**Examiner Terressa Boykin**  
**Primary Examiner**  
**Art Unit 1711**